K092710

510(k) Summary

Submitter Information: Pentax Medical Company, A Division of Pentax America, Inc.
102 Chestnut Ridge Road
Montvale, New Jersey 07645-1856

DEC - 2 2009

Name of Device

Trade Name:	ED-3490TK, Video Duodenoscope
Classification Name:	Duedenoscope and Accessories Flexible/Rigid {876.1500} tier 2
Product Code:	FDT

Predicated Device(s) Information

Model, Description	Manufacturer	PMN #
ED-3410, Video Duodenoscope	Pentax Medical Company	K963056
EPK-i, Video Processor	Pentax Medical Company	Jointly Submitted

Device Description
The ED-3490TK, Video Duodenoscope, must be used with a Video Processor (software controlled device). The endoscope has a flexible insertion tube, a control body and umbilicus. The umbilicus provides connection to the video processor. The control body includes controls for up/down/left/right angulation, air/water delivery, suction and an accessory inlet port. The device contains light carrying bundles to illuminate the body cavity and a charge couple device (CCD) to collect image data. The instrument contains a working channel through which biopsy devices or other devices may be introduced. The Video Processor, EPK-i, contains a 300 watt short Arc Xenon lamp which provides white light that is focused at the connected video endoscope lightguide prong. The endoscope light carrying bundles present the light to the body cavity and the CCD collects image data. Image data and other screen display information are formatted and presented to the video outputs of the video processor for display.

Intended Use:
The ED-3490TK, Video Duodenoscope is intended to provide optical visualization (via a video monitor) of, and therapeutic access to, the Upper Gastrointestinal Tract and Biliary Tract. The Upper Gastrointestinal Tract and Biliary Tract includes but is not limited to, the organs; tissues; and subsystems: Esophogus, Stomach, Duodenum, Common Bile Duct, Hepatic Duct and Cystic Duct. The instrument is introduced per orally when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Comparison to Predicated Device(s)
The submission for substantial equivalence included literature describing the system including; specifications, the identification of standard set components and optional accessories, tables to summarize the comparisons to the predicated device(s), and system performance testing. The submission for substantial equivalence is not based on an assessment of clinical performance data.

Prepared by: Paul Silva Signature: Paul Silva Date: 2009.08.26
Control Number: ED-3490TK

Revision: a

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC - 2 2009

Ms. Lisa Lancia
Regulatory Affairs Assistant
Pentax Medical Company
102 Chestnut Ridge Road
MONTVALE NJ 07645-1856

Re: K092710
Trade/Device Name: PENTAX ED-3490TK, Video Duodenoscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDT
Dated: August 6, 2009
Received: September 3, 2009

Dear Ms. Lancia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092710

Device Name: PENTAX ED-3490TK, Video Duodenoscope

Indications For Use:
The ED-3490TK, Video Duodenoscope, is intended to provide optical visualization (via a video monitor) of, and therapeutic access to the Biliary Tract via the Upper GI Tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: Esophogus, Stomach, Duodenum, Common Bile, Hepatic, and Cystic Ducts. This instrument is introduced via the mouth when indications consistent with the need for procedure are observed in adult and pediatric populations.

Prescription Use ___√____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092710